IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER AG and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer AG (Bayer AG and Bayer Pharma AG are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Lupin Limited of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs' 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Lupin

5. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, with a place of business at B/4 Laxmi Towers, Bandra Kurla complex, Bandra (E), Mumbai 400051, India.

6. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

7. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Limited, and is controlled and dominated by Lupin Limited.

8. On information and belief, Lupin Limited is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Lupin Limited, acting in concert with Lupin

Pharmaceuticals, Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Lupin Limited, acting in concert with Lupin Pharmaceuticals, Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. acted in concert to prepare and submit ANDA No. 208555 for Lupin Limited's 2.5 mg rivaroxaban tablets ("Lupin's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Lupin Limited.

10. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Lupin's ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 208555, Lupin Limited and Lupin Pharmaceuticals, Inc. will act in concert to market, distribute, offer for sale, and sell Lupin's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Lupin."

12. On information and belief, following any FDA approval of ANDA No. 208555, Lupin knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs 1-12 as if each is fully set forth herein.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because, among other things, Lupin Pharmaceuticals, Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Lupin Pharmaceuticals, Inc. is a corporation formed under the laws of the state of Delaware, and has appointed registered agents in Delaware (The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE) to accept service of process. It therefore has consented to general jurisdiction in Delaware.

16. Upon information and belief, Lupin Pharmaceuticals, Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in Delaware, and relies on contributions from Lupin Limited.

17. Upon information and belief, Lupin Pharmaceuticals, Inc., acting as the agent of Lupin Limited, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Lupin Limited or for which Lupin is the named applicant on approved ANDAs.

18. In addition, this Court has personal jurisdiction over Lupin because, among other things, on information and belief: (1) Lupin has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product in the United States, including in Delaware; and (2) Lupin will market, distribute, offer for sale, and/or sell Lupin's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 208555, and will derive substantial revenue from the use or consumption of Lupin's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 208555 is approved, the generic Lupin product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

19. Alternatively, if Lupin Limited's connections with Delaware, including its connections with Lupin Pharmaceuticals, Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Lupin Limited is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Lupin Limited in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

20. Lupin Limited and Lupin Pharmaceuticals, Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court, *see, e.g., Bayer Intellectual Property GmbH, et al., v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 17-1047-RGA (D.I. 9); *Genentech, Inc., et al. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 19-109-RGA (D.I. 10).

VENUE

21. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Limited is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

22. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

23. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

24. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

25. The ’310 patent, entitled “Reducing the Risk of Cardiovascular Events,” was duly and legally issued on November 10, 2020. The ’310 patent is attached as Exhibit A.

26. As set forth in greater detail in the ’310 patent, the claims of the ’310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, “A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that

are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

27. Bayer Pharma AG is the assignee of the '310 patent.

28. Bayer AG is an exclusive licensee under the '310 patent.

29. Janssen is an exclusive sublicensee under the '310 patent.

30. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with the 2.5 mg strength of XARELTO®.

COUNT I: INFRINGEMENT OF THE '310 PATENT

31. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

32. By letter dated January 15, 2021 ("Lupin's Notice Letter"), Lupin notified, *inter alia*, Plaintiffs that Lupin had submitted to the FDA ANDA No. 208555 for Lupin's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

33. In Lupin's Notice Letter, Lupin indicated that, in connection with its ANDA No. 208555, Lupin had filed a Paragraph IV Certification with respect to the '310 patent.

34. In Lupin's Notice Letter, Lupin stated that Lupin's ANDA Product contains rivaroxaban.

35. On information and belief, the proposed labeling for Lupin's ANDA Product directs a method of reducing the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). On information and belief, the proposed labeling for

Lupin's ANDA Product further directs the administration of Lupin's ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein Lupin's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

36. The purpose of ANDA No. 208555 was, *inter alia*, to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

37. Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208555, *i.e.*, prior to the expiration of the '310 patent.

38. On information and belief, the manufacture, use (including in accordance with and as directed by Lupin's proposed labeling for Lupin's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product will infringe at least claim 1 of the '310 patent.

39. In Lupin's Notice Letter, Lupin did not contest that the use of Lupin's ANDA Product in accordance with its proposed labeling would infringe the '310 patent, assuming the patent is valid.

40. Lupin has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product with its proposed

labeling immediately and imminently upon approval of ANDA No. 208555. On information and belief, by such activities, Lupin specifically intends to infringe the ’310 patent.

41. On information and belief, Lupin plans and intends to, and will, actively induce infringement of the ’310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

42. On information and belief, Lupin knows that Lupin’s ANDA Product with its proposed labeling is especially made or adapted for use in infringing the ’310 patent, and that Lupin’s ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. On information and belief, Lupin plans and intends to, and will, contribute to infringement of the ’310 patent immediately and imminently upon approval of ANDA No. 208555.

43. Lupin’s submission of ANDA No. 208555 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin’s ANDA Product was an act of infringement of the ’310 patent under 35 U.S.C. § 271(e)(2).

44. On information and belief, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin’s ANDA Product with its proposed labeling prior to the expiration of the ’310 patent.

45. Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin’s ANDA Product with its proposed labeling prior to the expiration of the ’310 patent.

46. The foregoing actions by Lupin constitute and/or will constitute infringement of the ’310 patent, active inducement of infringement of the ’310 patent, and/or contribution to the infringement by others of the ’310 patent.

47. Unless Lupin is enjoined from infringing the ’310 patent, actively inducing infringement of the ’310 patent, and contributing to the infringement by others of the ’310 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

48. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received the Lupin Notice Letter.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’310 PATENT

49. Plaintiffs incorporate each of the preceding paragraphs 1-48 as if fully set forth herein.

50. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Lupin on the other regarding Lupin’s liability for infringement and active inducement of infringement of the ’310 patent.

51. An actual case or controversy exists between Plaintiffs and Lupin with respect to infringement of the ’310 patent.

52. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Lupin’s ANDA Product will infringe and induce the infringement of the ’310 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Lupin has infringed the ’310 patent;

(b) A judgment ordering that the effective date of any FDA approval for Lupin to make, use, offer for sale, sell, market, distribute, or import Lupin’s ANDA Product, or any

product or compound the use of which infringes the ’310 patent, be no earlier than the expiration date of the ’310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Lupin, and all persons acting in concert with Lupin, from making, using, selling, offering for sale, marketing, distributing, or importing Lupin’s ANDA Product, or any product or compound the use of which infringes the ’310 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Lupin’s ANDA Product prior to the expiration of the ’310 patent will infringe and induce the infringement of the ’310 patent;

(e) A declaration that this is an exceptional case and an award of attorneys’ fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs’ costs and expenses in this action; and

Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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